BK150321
510(k) Summary

I. SUBMITTER

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II. DEVICE

Trade Name of Device: Trima Accel® system
Common or Usual Name: Automated Blood Component Collection System
Classification Name: Class II
Regulatory Class: In accordance with 21 CFR 864.9245(b), the classification for this device is Class II with special controls.
Product Code: GKT

III. PREDICATE DEVICE

The predicate device mentioned in this submission is listed below:

510(k) number	Clearance Date	Device Name/Brief Description
BK150269	6-August-2015	Wireless Solution and Labeling update

The reference devices mentioned in this submission is listed below:

510(k) number	Clearance Date	Device Name/Brief Description
BK040069	8-Sept-2004	Trima System Blood Component Sampling Accessory
BK140158	29 August 2014	Trima Accel Version 6.4

These predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

A. Device Identification

The Trima Accel system is an automated blood component collection system that uses centrifugal force to separate whole blood into platelet, plasma, and red blood cell components. These blood components are either collected into storage bags, or returned to the donor depending on the procedure selected at the time of collection. The Trima Accel system consists of three subsystems:

1. The Trima Accel system
2. Embedded software
3. Single use, Disposable Tubing Sets

The products collected depend on the disposable tubing collection set used, the donor specific parameters (donor's total blood volume, hematocrit, and platelet count) entered at the time of collection, and the procedure selected. Donor blood type may also be used to limit which blood components are collected. Depending on the disposable tubing set used, the Trima Accel system may collect the following products alone or in combination, depending on the approval of the disposable tubing set:

- Platelets Pheresis (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Plasma
- Plasma, Leukocytes Reduced
- AS-3 Red Blood Cells (single or double units)
- AS-3 Red Blood Cells, Leukocytes Reduced (single or double units) utilizing an integrated filter

The Trima Accel Larger integrated blood component sampling assembly is an integrated sampling assembly system with a reservoir of up to 35 mL capacity that allows bacterial contamination testing in platelet products.

B. Device Characteristics

The Trima Accel disposable sets are provided sterilized with ethylene oxide (EtO). There have been no changes neither to Trima Accel System or embedded software. The modification, subject of this submission, consists in a larger platelet sampler for bacterial testing which does not affect any material or disposable configuration.

C. Environment of Use

The operation of the Trima Accel system is performed by professionally-trained apheresis operators in a blood center or hospital laboratory environment. Operators are commonly trained on the principles of apheresis by their organization. Operators of the device have a variety of backgrounds and professional training, and the primary users are expected to be nurses and laboratory technicians.

D. Device Description

Terumo BCT has proactively changed the Anticoagulant (AC) connector on the Trima Accel® disposable blood tubing sets from a standard spike to a specialized luer that is not compatible with any other connection on the set to avoid misconnections. The AC connector is used by operators to attach a bag of anticoagulant ACD-A to the Trima Accel system. To facilitate customer transition to the new luer connector, an AC Connection Adapter is also being added as an optional accessory in order to connect the tubing sets containing the new AC luer connector to ACD-A solution sets with a spike receptor.

The larger Trima Blood Component Sampling Assembly is a sampling system integrated to the Trima Accel disposable set which allows aseptic removal of a sample from the platelet bag without

need for sterile docking. The proposed modification is to increase the sampler reservoir and provide additional graduation marks on the reservoir to facilitate sampling larger platelet volumes.

The instruction for splitting products into additional products bags was modified to guide the users in how to split the product into up to four bags, post collection, in the rare instances when a collected triple product could be split into four bags that are still within the storage specifications and platelet yield requirements.

E. Materials of Use

There is no material changes provided in this notification. The proposed version of the system is equivalent to the legally marketed predicate with respect to materials and biocompatibility.

F. Key Performance Specifications/Characteristics of the Device

The new AC connector (a luer connector to replace current spike connector) was designed to ensure that the connection between the ACD-A solution bag and the AC line on the tubing set is secure and allows the flow of AC through the Trima Accel system tubing set. The intent of the design is also to prevent misconnections with other apheresis solutions by providing a unique connection modality for ACD-A. The Anticoagulant Connection Adapter was designed to facilitate transition to the new AC luer connection modification.

The larger blood component sampling assembly, which is integrated to the tubing set, allows sampling the platelet product(s) after collection. Functions and correct usage can be found in the Operator's Manual.

V. Intended Use / Indications for Use

The Trima Accel system is an automated blood cell separator intended for use in collecting blood components for later transfusion into patients.

Depending on the disposable tubing set used, the Trima Accel system has been cleared to collect:

- Double ACD-A/AS-3 Red Blood Cells (leukocytes reduced or not leukoreduced)

Or the following products alone or in combination:

- ACD-A/AS-3 Red Blood Cells
- ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced utilizing an integrated filter (TLR gravity drain filter or Auto RBC filter)
- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (Isoplate) (single or double units)
- Platelets Pheresis, Platelet Additive Solution (Isoplate) (triple units) Note: For triple platelet collections (platelet yield greater than 9.0 x 10e11), the product can be labeled as leukocytes reduced if the residual WBC content is tested and determined to meet the U.S. leukoreduction specifications. Products that do not meet the U.S. leukoreduction specifications must be discarded.
- Plasma

- Fresh Frozen Plasma and Fresh Frozen Plasma, Leukocytes Reduced
  - Must be prepared and placed in a freezer at -18 °C or colder within 8 hours of collection.
- Plasma Frozen Within 24 Hours After Phlebotomy (PF24) and Plasma Frozen Within 24 Hours After Phlebotomy, Leukocytes Reduced
  - Must be stored at 1°C to 6°C within 8 hours of collection and placed in a freezer at -18 °C or colder within 24 hours of collection.
  - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) and Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy, Leukocytes Reduced
  - Can be stored at room temperature for up to 24 hours after collection. Product must be placed in a freezer at -18 °C or colder within 24 hours of collection.
  - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Source Plasma

Platelet Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. Platelets Pheresis, Leukocyte Reduced, Platelet Additive Solution (Isoplate) (single or double units) may be further processed (e.g., irradiated, divided). Platelets Pheresis, Platelet Additive Solution (Isoplate) (single or double units) may **not** be manufactured from products that do not meet leukocyte reduction product standards.

The Trima Blood Component Sampling Assembly, which is either integrated into the disposable tubing sets or as an accessory for sterile connection, is intended to allow aseptic removal of a sample from the platelet bag for subsequent bacterial or other applicable testing. The Sampling Assembly does not have contact with blood fluids that are reinfused to a donor or patient.

The storage conditions of the Trima Platelet bag (ELP bag) have been verified for storage up to 7 days post-collection in 100 % Plasma and up to 5 days in Isoplate Solution (PAS-F). Additionally, for storage up to 7 days, every product must be tested with a bacterial detection device cleared by FDA and labeled as a “safety measure”.

- Adequate studies have not been performed to evaluate the effect of gamma irradiation or freezing on the quality of ACD-A/AS-3 red blood cells products (RBCs) collected with gravity drain leukoreduction process (TLR filter) on the Trima Accel system.

- Studies have not been performed to support gamma irradiation or freezing of ACD-A/AS-3 RBCs collected with an integrated in-line RBC leukoreduction filter(s) (Auto RBC filter) on the Trima Accel system.

Rx Only.

Acceptance Criteria and Parameters:

RBCs collected on the Trima Accel system using the Auto RBC feature as either a single unit or double units, with continuous RBC leukoreduction, and stored in ACD-A/AS-3 for 42 days met the following acceptance criteria required by the FDA-CBER:

Primary Outcomes

95% probability and a one-sided 95% confidence limit:

- the number of contaminating leukocytes per unit is less than 5 million
- the recovery of RBCs after leukoreduction is greater than 85%
- RBC hemolysis is less than 1.0%

The mean recovery at 24 hours for each unit is ≥75% with standard deviation ≤9%; and the one sided 95% lower confidence limit for the population proportion of successes is >70% (successes = individual units recovery ≥75%).

Secondary Outcomes

The results of biochemical tests for ATP and Potassium levels at the end of storage failed to show with 95% confidence that greater than 95% of the products will be within 20% of the Control product. Results of ATP levels for Test for a single RBC collection were not significantly different from Control by a paired t test analysis (p-value = 0.80). Results of ATP levels for Test for double RBC collections were significantly better than Control by a paired t test analysis (two-sided p-value = 0.014). Results of Potassium levels for Test for a single RBC collection were significantly better than Control by a paired t test analysis (p-value = 0.0354). Results of Potassium levels for Test for double RBC collections were not significantly different from Control by a paired t test analysis (two-sided p-value = 0.566).

The pH results support the conclusion with 95% confidence that more than 95% of the products will have a difference between Test and Control of less than 0.5 pH units at the end of RBC shelf life. The clinical significance of the secondary outcomes is unknown.

The Trima Accel system includes a modified platelet post-count algorithm. U.S. customers should not set the minimum post-count below 100,000/ μL.

The following table summarizes the plasma product parameters from a paired study comparing PF24RT24 (apheresis plasma held at room temperature and frozen 24 hours post-collection) and FFP (apheresis plasma held at room temperature and frozen 8 hours post-collection).

Summary of PF24RT24 (Test) and FFP (Control) Plasma Product Parameters (N=52)							
Coagulation Assay	**Mean (SD)**		**Median**		**(Minimum, Maximum)**		**Mean Difference (Test- Control) (95% Confidence Interval)**
	Control	**Test**	**Control**	**Test**	**Control**	**Test**	
PT (seconds)	12.0 (0.6)	12.1 (0.6)	11.8	12.0	10.7, 13.7	10.9, 13.8	0.1 (0.1, 0.2)
aPTT (seconds)	37.9 (3.9)	38.5 (3.8)	37.7	38.5	31.1, 47.7	31.6, 48.6	0.6 (0.2, 0.9)

Factor V (IU/dL)	100.4 (17.6)	99.5 (16.5)	102.5	100.5	52, 138	52, 136	-0.9 (-2.0, 0.2)
Factor VIII (IU/dL)	79.8 (25.0)	72.6 (24.1)	74.0	67.5	37, 163	36, 157	-7.2 (-9.3, -5.1)
Factor XI (IU/dL)	73.5 (11.4)	73.8 (11.0)	71.5	71	53, 109	52, 103	0.3 (-0.4, 1.0)
vWF (IU/dL)	91.7 (29.1)	89.4 (28.2)	90.5	87	44, 145	41, 145	-2.3 (-4.2, -0.4)
Protein C (IU/dL)	97.9 (14.0)	94.3 (13.4)	99	98	65, 123	62, 126	-3.7 (-5.5, -1.9)
Protein S (IU/dL)	93.3 (20.0)	83.0 (19.2)	91.5	80.5	53, 161	48, 145	-10.3 (-12.4,-8.2)
AT III (IU/dL)	103.1 (7.7)	102.8 (7.8)	103	102.5	85, 120	85, 116	-0.3 (-1.4, 0.9)
Factor VIIa	2.6 (1.2)	2.7 (1.3)	2.4	2.3	0.6, 6.1	1.2, 6.4	0.1 (-0.3, 0.4)
FPA	9.2 (12.2)	9.9 (11.1)	4.0	4.9	0.6, 57.5	0.4, 44.9	0.6 (-3.4, 4.7)

VI. TECHNOLOGICAL COMPARISON

The modified Trima Accel System: anticoagulant connection modification (from spike to luer), new Anticoagulant Connection Adapter, larger integrated blood component sampling assembly, and modification of the instructions for splitting products into additional product bags, do not in any way change the system's fundamental scientific technology or principle of operation; that is, the separation of blood into its components using centrifugation.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

A. Mechanical Testing

A variety of testing was performed for the Anticoagulant (AC) connector modification (from spike to a luer), new Anticoagulant Connection Adapter, and larger integrated blood component sampling assembly; e.g. flow rate, bond and leak testing. The data are summarized in Section 5; the results met acceptance criteria. Verification bench testing has demonstrated that the Trima Accel disposable blood tubing set with Anticoagulant (AC) connector modification (from spike to a luer), Anticoagulant Connection Adapter, and larger integrated blood component sampling assembly modification, performs as intended, and is substantially equivalent to the predicate device.

B. Biocompability Testing

The biocompatibility evaluations for the Anticoagulant (AC) connector modification (from spike to a luer), new Anticoagulant Connection Adapter, and larger integrated blood component sampling assembly modification, were conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Standard evaluation of the biocompatibility for blood contact materials is conducted whenever a new material or other variable is introduced into disposable sets. No material changes were made as a result of the Anticoagulant connector modification (from spike to a luer), new Anticoagulant Connection Adapter, and larger integrated blood component sampling assembly.

C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were not required as a result of the Anticoagulant (AC) connector modification (from spike to a luer), new Anticoagulant Connection Adapter, and larger integrated blood component sampling assembly.

D. Software Verification and Validation Testing

There are no changes to the software as a result of the Anticoagulant (AC) connector modification (from spike to a luer), new Anticoagulant Connection Adapter, and the larger integrated blood component sampling assembly. The software is identical to previously cleared software for the Trima Accel system.

E. Sterility Testing

Trima Accel system products are validated to ensure that they are not released until acceptance criteria are met according to the requirements outlined in ANSI/AAMI/ISO 11135-1:2007. When sterilized with the validated ethylene oxide cycle, the product has a sterility assurance level (SAL) of $\leq 10^{-6}$. There were no changes to the sterilization process or SAL as a result of the Anticoagulant (AC) connector modification (from spike to a luer), new Anticoagulant Connection Adapter, and larger integrated blood component sampling assembly.

F. Stability/Shelf Life Testing

The shelf life of the Trima Accel system disposable sets has been determined to be 2 years.

G. Clinical Studies

The Anticoagulant (AC) connector modification (from spike to a luer), new Anticoagulant Connection Adapter, larger integrated blood component sampling assembly, and modified instructions for splitting products did not require clinical data or otherwise impact safety and efficacy of the Trima Accel system.

VIII. CONCLUSIONS

The modifications subject of this submission are substantially equivalent to the predicate and reference devices as they do not affect the intended use and do not impact safety and efficacy of the Trima Accel system.